PATENT
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:	
Karl T. Kraemer and Manfred Bohn	Group Art Unit: 1617
Application No.: 09/425,742	Examiner: L. Wells
Filed: October 22, 1999	
CPA filed: November 1, 2002	
For: COMPOSITIONS FOR TOPICAL APPLICATION HAVING ANDROGENIC ACTIONS	

Mail Stop Appeal Brief--Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

APPEAL BRIEF UNDER 37 C.F.R. § 1.192

In support of the Notice of Appeal filed on September 29, 2003, and pursuant to 37 C.F.R. § 1.192, Appellants present three copies of their brief and a check in the amount of $330.00 for the fee under 37 C.F.R. § 1.17(c). A Petition for Extension of Time (One Month) and fee therefor accompanies this appeal brief, extending the period for submitting the brief until December 29, 2003. Please grant any further extensions of time required to enter this Appeal Brief and charge any additional required fees to our Deposit Account No. 06-0916.

Appellants also file herewith an Amendment after Appeal under 37 C.F.R. § 1.116 and respectfully request entry thereof. The accompanying Amendment should

render moot the pending rejection of claim 10 under 35 U.S.C. § 112, ¶ 2, leaving only prior art rejections to be considered in this appeal.

I. Real Party In Interest

The real party in interest is Aventis Pharma Deutschland GmbH, Assignee of the present application.

II. Related Appeals and Interferences

To the best of the undersigned's knowledge, there are no related appeals or interferences known to Appellants, the Appellants' legal representative, or Assignee which will directly affect or be directly affected by or have a bearing on the Board's decision in the present appeal.

III. Status Of Claims

If the accompanying Amendment after Appeal under 37 C.F.R. § 1.116 is not entered, then claims 1-23 and 28-38 are pending and appealed. Claims 24-27 have been canceled without prejudice or disclaimer, and claims 3, 9, and 30-38 are withdrawn as non-elected.

If the accompanying Amendment under 37 C.F.R. § 1.116 is entered, then claims 1-23, 28-29, and 39-44 are pending and appealed. Claims 24-27 and 30-38 have been canceled without prejudice or disclaimer, and claims 3 and 9 are withdrawn as non-elected.

IV. Status Of Amendments

The Amendment filed on June 2, 2003 has been entered. *See* Final Office Action at 1-2. Appendix A presents the claims in the form pending after that Amendment. Appellants file herewith an Amendment after Appeal under 37 C.F.R. § 1.116. If this Amendment is entered, the reader is directed to Appendix B for the claims on appeal.

V. Summary Of Invention

Appellants have invented a new method for delivering particular therapeutic compounds to the skin. The invention therefore relates to compositions, processes for making those compositions, and methods of treatment using those compositions. Specifically, at least some compositions according to the claimed invention "compris[e] one or more topical antiandrogens[,] . . . a physiologically tolerated volatile solvent or solvent mixture, a plasticizer, and one or more physiologically acceptable film-forming agents." Specification at 4. These compositions may "form flexible films which adhere to the scalp" or other skin, and may be "capable of releasing the active compounds employed in a controlled manner and over a certain period of time." *Id.* In at least some embodiments of the claimed invention, the claimed compositions enhance delivery of the active compound by eliminating precipitation of the active compounds at the application site. *Id.*

Independent claim 1 recites a composition comprising at least one physiologically tolerated film-forming agent, at least one physiologically tolerated solvent, at least one plasticizer, and a compound of the formula I or a stereoisomeric form or a

physiologically tolerated salt of any of the foregoing. Support for this claim can be found, among other places, in the specification at pages 4-8.

Independent claim 22 recites a process for making a product for treatment of androgenic alopecia, comprising the step of forming said product by bringing together certain ingredients recited in the claim. Support for this claimed invention can be found, among other places, in the specification at page 13, lines 9-12; and on page 14. Claim 23 makes a similar claim for preparing a composition intended for treating seborrhea or acne, while independent claim 28 recites a process for treatment of seborrhea or acne. Support for these claims can be found, among other places, in the specification on page 13, lines 14-16.

Independent claim 29 recites a cosmetic composition comprising certain ingredients that are the same as or similar to those set forth in claim 1. Support for this claim appears, among other places, in the specification at page 14, lines 1-2.

Independent claim 30, which would be canceled by the Amendment after Final if it is entered, recites a method of treating skin substantially without hair cover. Support for this claim can be found, among other places, in the specification at pages 18-19.

Claims 1, 22, 23, 24, 28, 29, and 30 also state that the "compound of formula I is released from the film formed by application of said composition to a skin surface." Support for this statement can be found, among other places, in the specification at page 10, lines 1-8.

VI. Issues

A. Whether claim 10 is indefinite under 35 U.S.C. § 112, ¶ 2, if Appellants' Amendment under 37 C.F.R. § 1.116 is not entered.

B. Whether claims 1, 2, 4-8, 10-13, 16-17, 22-23, 28-29, and by extension, new claims 39-44 are rendered obvious under 35 U.S.C. § 103 over *Cretois* (U.S. Patent No. 5,558,859) in view of *Dubois* (U.S. Patent No. 6,162,444).

C. Whether claim 14 is rendered obvious under 35 U.S.C. § 103 over *Cretois* in view of *Dubois,* in further view of *Lai* (U.S. Patent No. 5,916,910).

D. Whether claim 15 is rendered obvious under 35 U.S.C. § 103 over *Cretois* in view of *Dubois,* in further view of *Ismail* (U.S. Patent No. 5,541,220).

E. Whether claim 19 is rendered obvious under 35 U.S.C. § 103 over *Cretois* in view of *Dubois,* in further view of WO 92/21317 ("the '317 PCT application").

F. Whether claims 20-21 are rendered obvious under 35 U.S.C. § 103 over *Cretois* in view of *Dubois,* in further view of WO 91/19701 ("the '701 PCT application").

VII. Grouping Of Claims

Claims 1-2, 4-8, 10-13, 16-17, 22-23, 28-29, and 39-44 stand or fall together.

Claim 14 stands alone.

Claim 15 stands alone.

Claim 19 stands alone.

Claims 20-21 stand or fall together.

VIII. Argument

A. Claim 10 Is Definite.

Whether or not Appellants' Amendment after Appeal under 37 C.F.R. § 1.116 is entered, claim 10 is not indefinite under 35 U.S.C. § 112, ¶ 2.

Claim 10 stands rejected under 35 U.S.C. § 112, ¶ 2, for allegedly being indefinite. Final Office Action at pages 3-4. The Examiner points out that original claim 10 recites, "acrylate copolymers, acrylate/acrylamide copolymers, and acrylate/octylacrylamide copolymers," and alleges that such language is indefinite for reciting a forbidden range within a range. *Id.* at page 3. Appellants respectfully traverse this rejection.

Original claim 10 does not recite an improper "range within a range." The Examiner's allegation is more akin to an assertion that the claim recites a Markush group comprising a genus and a subgenus within that genus. For sake of argument, it might be said that "acrylate copolymers" states a genus, and "acrylate/acrylamide copolymers" states a subgenus within that genus. This alleged "double inclusion" is perfectly acceptable, so long as this does not render the claim indefinite or result in undue multiplicity. *See* M.P.E.P. § 2173.05(h). That section of the M.P.E.P. illustrates: "For example, the Markush group, 'selected from the group consisting of amino, halogen, nitro, chloro, and alkyl' should be acceptable even though 'halogen' is generic to 'chloro.' " *Id.*

Without acquiescing to the rejection, Appellants file herewith an Amendment after Appeal under 37 C.F.R. § 1.116 that divides original claim 10 into amended claim 10

and new claims 39-44. This amendment renders the rejection moot, since any possible subgenus appears in a claim separate from any possible genus.

This rejection, therefore, should be reversed, regardless of whether Appellants' amendment is entered.

B. Claims 1-2, 4-8, 10-13, 16-17, 22-23, 28-29, and 39-44 Are Patentable over *Cretois* in View of *Dubois*.

Claims 1-2, 4-8, 10-13, 16-17, 22-23, and 28-29 have been rejected under 35 U.S.C. § 103(a) as allegedly being obvious over *Cretois* in view of *Dubois*. Final Office Action at pages 4-5 (citing Office Action dated January 22, 2003). The Examiner has acknowledged that *Cretois* "lacks instant formula (I) and 5-alpha-reductase inhibitors," and has cited *Dubois* to overcome these deficiencies. January Office Action at page 4. Appellants respectfully disagree with this rejection. Since new claims 39-44 claim the subject matter of rejected claim 10, Appellants also contend that those new claims are patentable over *Cretois* in view of *Dubois*.

1. The claimed invention must be considered as a whole.

As an initial matter, the claimed invention should be examined as a whole. In the Final Office Action, the Examiner states that "the recitation of 'application of said composition to a skin surface', is not given patentable weight" because it is a mere recitation of an intended use. Final Office Action at page 5. Appellants contend that the Examiner has failed to consider the claimed invention, and in particular the relevant phrase, as a whole. Appealed claims 1, 22, 23, 24, 28, and 29, state that the "compound of formula I is released from the film formed by application of said composition to a skin surface." The phrase, taken as a whole, provides a difference

from compositions that do not release the compound of formula I under the same conditions. Application of a claimed compositions to the skin is not a "mere recitation of an intended use," it is a necessary use. Ignoring this claim language would allow the skilled artisan to look for active compound release under any conditions, and not merely upon administration to the skin. "'All words in a claim must be considered in judging the patentability of that claim against the prior art.'" M.P.E.P. § 2143.03 (quoting *In re Wilson,* 424 F.2d 1382, 1385, 165 U.S.P.Q. 494, 496 (C.C.P.A. 1970)). Accordingly, this claim language should be given weight.

2. The Examiner has failed to make a *prima facie* case of obviousness.

Appellants respectfully contend that a *prima facie* case has not been made. To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all of the claim limitations. M.P.E.P. § 2143.

a. The proposed combination lacks motivation because *Cretois* and *Dubois* treat different tissues of the body.

The combination proposed by the Examiner lacks the requisite motivation to combine, because *Cretois* and *Dubois* treat different tissues of the body. *Cretois* teaches hair, eyelash, and nail compositions, and exemplifies hair styling mousses and mascaras-all compositions for treating keratinous tissue. *See Cretois* at cols. 7-9. In contrast, *Dubois* teaches skin compositions useful for treating cancers and skin afflictions-that is, compositions for treating dermal tissues. *See Dubois* at col. 6, ll. 49-

59. One of ordinary skill in the art would not combine a hair treatment with a skin treatment without significant hindsight reasoning.

To allege the requisite motivation, the Examiner relies on *Dubois'* disclosure regarding "treatment of hirsutism, androgenic alopecia, and hyperpilosity, which are all conditions related to hair growth." Final Office Action at page 6 (citing *Dubois* at col. 6, ll. 57-59). From this, the Examiner derives that "Dubois does teach applying his compositions to the hair." *Id.* However, *Dubois'* invention works only by application and penetration into the skin, and not by application to hair. "The topical use of an active ingredient encapsulated in liposomes allows the active ingredient to be concentrated in the sebaceous glands to obtain a higher and longer-lasting concentration in the epidermis and in the dermis in vivo . . . ." *Dubois* at col. 4, ll. 42-45. *Dubois* refers to these liposomes containing the active ingredient as "vesicles." *See id.* at col. 4, ll. 13-16. *Dubois'* vesicles or "liposomes containing the active ingredient localize the penetration into the epidermis and into the sebaceous glands while minimizing passage into the circulatory system." *Id.* at col. 6., ll. 45-48. Therefore, the skilled artisan would read *Dubois* to conclude that it is treatment of skin that affects treatment of conditions related to hair growth. *See Dubois* at col. 6, ll. 45-48. In addition, the Examiner offers no evidence that treating hair will treat hirsutism, androgenic alopecia, or hyperpilosity. *See* Final Office Action at page 6. The leap from *Dubois'* treatment of hair-growth related conditions to actual treatment of the hair cannot be made. Thus, the Examiner's statement, "Dubois does teach applying his compositions to the hair" is incorrect. *Id.*

In contrast, *Cretois* treats "exoskeletal parts" rather than skin. *Cretois* at col. 1, ll. 6-8. "Exoskeletal parts include the hair, the eyelashes, the eyebrows, the fingernails or

the toenails." *Cretois* at col. 2, lines 6-8. For the treatment of these parts, *Cretois* describes a "hair styling mousse" in Example 1, another "hair styling mousse" in Example 2, a "hair-setting lotion" in Example 3, and a "mascara" in Example 4. *Id.* at cols. 7-9. *Cretois* does not disclose a "skin composition," a fact which the Examiner acknowledges is "correct." Final Office Action at page 6.

Appellants therefore maintain that *Cretois* and *Dubois* teach compositions directed to different purposes. Thus, the motivation offered to support this rejection rests on the false assumption that *Dubois* teaches treating hair.

A much closer rejection was reversed by the Federal Circuit in *In re Geiger,* 815 F.2d 686, 2 U.S.P.Q.2d (BNA) 1276 (Fed. Cir. 1987). The *Geiger* applicants claimed a method of inhibiting scale formation and corrosion in a cooling water system using a composition comprising three ingredients. The references individually taught combinations of perhaps two of applicants' three ingredients in compositions for preventing scale in boiling or cooling water systems, with all three ingredients being disclosed by several references.

Yet the Federal Circuit found no suggestion to combine all three ingredients in one composition for the purpose of inhibiting scaling and corrosion in a cooling water system. It was not enough that the three ingredients appeared separately in the prior art, even in compositions useful for the same purpose as applicants' claimed method. The court rejected the PTO's finding of a *prima facie* case of obviousness, stating, "At best, in view of these disclosures, one skilled in the art might find it obvious to try various combinations of these known scale and corrosion prevention agents. However,

this is not the standard of 35 U.S.C. § 103." *In re Geiger,* 815 F.2d at 688, 2 U.S.P.Q.2d at 1278.

In the present case, *Cretois* and *Dubois* are not even directed to compositions disclosed for the same purpose. *Cretois* teaches compositions for treating exoskeletal parts such as hair, eyelashes, eyebrows, fingernails and toenails. *Cretois* at col. 2, ll. 6-8. Dubois teaches compositions for the topical treatment of skin. *Dubois* at col. 6, ll. 41-44. If the rejection in *Geiger* was reversed, then the present rejection also should be reversed.

b. The proposed combination lacks motivation, because *Dubois* does not teach an "antiseborrheic agent."

The Examiner seeks further motivation to combine in *Cretois'* and *Dubois'* alleged mutual teaching of anti-seborrheic agents. Final Office Action at page 7; *see also* January Office Action at 4. "Cretois teaches the addition of antiseborrhoiec agents to his composition and . . . the compound of formula (I), taught by Dubois, is taught as an antiseborrhoiec agent[.]" *Id.* The Examiner has mischaracterized the teaching of *Dubois*. *Dubois* states:

> The compositions of the invention can also be used as medicaments for the treatment of adenomas and neoplasias of the prostate, for combating benign hypertrophy of the prostate, for the treatment of benign or malignant tumors, the cells of which contain particularly [sic] androgen receptors. There can particularly be mentioned mainly cancers of the breast, the skin and the ovaries but also cancers of the bladder, the lymphatic system, the kidney, the liver. Moreover, the compositions can also be used in the treatment of hirsutism, acne, seborrhea, androgenic alopecia, hyperpilosity and in cosmetology.

Dubois at col. 6, ll. 49-59. *Dubois* thus does not state, as the Examiner alleges, that *Dubois'* compound of formula (I) is an antiseborrheic agent. Rather, *Dubois* merely

relates that the disclosed compositions can be used in the treatment of a diverse array of ailments, among them seborrhea.

Following the above passage, *Dubois* clarifies that additional ingredients may be needed to treat the listed ailments. Antibiotics such as "a derivative of azelaic acid or fusidic acid, erythromycin or . . . a derivative of the retinoids" may be added to the vesicles for the treatment of acne. *Dubois* at col. 6, ll. 61-64. "5-reductase inhibitor . . . or azelaic acid or a blocking agent of the androgen receptors" can be added "for the treatment of acne, alopecia or hirsutism," or a product may be added for "stimulating hair growth such as Minoxidil for the treatment of alopecia." *Id.* at col. 6, l. 61 - col. 7, l. 3. Also, *Dubois'* examples of the inventive compositions all include α-tocopherol, which is Vitamin E, an ingredient known to treat skin. *Id.* at col. 11, ll. 47, 60; *see also* "Vitamin E," THE MERCK INDEX 1712 (Susan Budavari ed., 12th ed., 1996)(attached hereto as Ex. 1). Therefore, while the ordinarily skilled artisan might conclude that the disclosed compositions act as novel vehicles for delivering known therapeutics to the skin, he would not necessarily conclude that *Dubois'* compound of formula (I) would be therapeutically active in any of the given ailments, based on *Dubois'* disclosure.

c. The *prima facie* case fails for lack of motivation and reasonable expectation, because it is not taught or suggested how *Dubois'* vesicles in *Cretois'* compositions would reach skin intact.

The Examiner next alleges that the ordinarily skilled artisan would be motivated to combine *Dubois'* composition with *Cretois'* composition *en masse*. Final Office Action at 7. "[T]hus, one of skill in the art would be motivated to add the liposomes containing formula (I) of Dubois into the composition of Cretois because of the expectation of achieving an anti-seborrhoiec composition that is more effective and

longer lasting, and which does not result in adverse side-effects as a result of seeping into the circulatory system." *Id.; see also* January Office Action at 4-5. This logic fails on several points.

First, the Examiner has failed to show that the skilled artisan would reasonably expect that *Dubois'* vesicles would be released from *Cretois'* compositions and reach the skin intact to deliver their "more effective and longer lasting" therapeutic effect. This is because *Cretois* teaches that certain compounds will act to form shape-retaining compositions, whereas *Dubois* teaches that the same or similar compounds will act as therapeutic delivery vehicles. These two actions are so inconsistent with each other as to defeat the skilled artisan's reasonable expectation of success in the proposed combination.

To illustrate, *Dubois* teaches that sphingolipids can be used as mobile, therapeutic delivery vehicles. Sphingolipids appear listed among the substances useful for forming *Dubois'* vesicles. *Dubois* at col. 4, l. 26. These vesicles provide "optimal penetration of the active ingredient through the skin." *Id.* at col. 6, ll. 43-44. This penetration requires intact vesicles to be applied to the skin. "According to the invention, the liposomes [vesicles] containing the active ingredient localize the penetration into the epidermis and into the sebaceous glands while minimizing passage into the circulatory system." *Id.* at col. 6, ll. 45-48. Accordingly, the sphingolipids forming *Dubois'* vesicles containing the active ingredient must be available to penetrate the skin.

Cretois teaches, however, that the Examiner's proposed combination of *Dubois'* sphingolipids with vinylpyrrolidone polymers will immobilize the sphingolipids. *Cretois'*

compositions contain "at least one ceramide and/or one glycoceramide and at least one vinylpyrrolidone polymer." *Cretois,* Abstract. Ceramides and glycoceramides are sphingolipids. *See* CHRISTOPHER K. MATHEWS & K.E. VAN HOLDE, BIOCHEMISTRY 674-78 (2d ed. 1996)(attached hereto as Ex. 2); *see also* January Office Action at 4. *Cretois'* combination of "ceramides and/or glycoceramides with vinylpyrrolidone polymers" results "especially [in] a remarkable improvement in the shape-retention of the hair style over time. This discovery is the basis for the present invention." *Cretois* at col. 1, ll. 28-34. One of ordinary skill in the art, considering Cretois' disclosure, would understand that the sphingolipids react or interact with the vinylpyrrolidone polymers to cause this shape-retaining effect, for example, by immobilizing the sphingolipid on the hair in a film formed with the vinylpyrrolidone polymer.

Such immobilization is inconsistent with the therapeutic delivery required by *Dubois*. *Cretois'* immobilization of the sphingolipid destroys the requisite reasonable expectation that the sphingolipid would be released to work in accordance with *Dubois*.

Second, even if *Cretois'* compositions release *Dubois'* vesicles on the hair, the Examiner has not shown how *Dubois'* vesicles make their way from the hair to the skin. More specifically, the skilled artisan is not taught or suggested to reasonably expect that *Dubois'* vesicles are released from *Cretois'* composition to migrate from the hair to the skin intact. The Examiner's proffered motivation rests on an expectation of "a more effective and longer lasting" therapeutic effect (Final Office Action at 7), which requires that *Dubois'* vesicles reach the skin intact. *See Dubois* at col. 6, ll. 45-48. The skilled artisan would not reasonably expect this to happen without some mechanism of migration. The Examiner suggests none.

Third, the Examiner offers no evidence that the resulting composition would still work for its alleged intended purpose, the treatment of seborrhea. *See* Final Office Action at 7 (finding motivation from "the expectation of achieving an anti-seborrheic composition"); *see also* January Office Action at 4-5. *Dubois* teaches compositions that may be useful for treating seborrhea when applied to the skin. *Dubois* at col. 6, ll. 57-59. If that skin composition is enclosed by a polymeric hair-styling composition and held to the hair, the skin composition will not reach the skin. Because *Dubois'* vesicles would not reach the skin, they would not confer therapeutic benefit to the skin, and so would be unsatisfactory for treating seborrhea. "If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." M.P.E.P. § 2143.01 (citing *In re Gordon,* 733 F.2d 900, 221 U.S.P.Q. 1125 (Fed. Cir. 1984)). Therefore, the proposed modification lacks the requisite motivation for this additional reason.

Fourth, by applying a skin composition to the hair and expecting it to migrate to the skin, the Examiner's proposed modification improperly changes the principle of operation of *Dubois.* "If the proposed modification or combination would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious." M.P.E.P. § 2143.01 (citing *In re Ratti,* 270 F.2d 810, 123 U.S.P.Q. 349 (C.C.P.A. 1959)). *Dubois'* vesicles work under the principle of "optimal penetration of the active ingredient through the skin." *Dubois* at col. 6, ll. 43-44. This penetration requires intact vesicles to be applied to the skin. "According to the invention, the liposomes containing the active ingredient localize the penetration into the epidermis and into the sebaceous glands

while minimizing passage into the circulatory system." *Id.* at col. 6, ll. 45-48. Introducing the steps of (a) releasing the vesicles from a hair composition, and (b) transferring the vesicles from the hair to the skin, dramatically changes the principle of operation of *Dubois'* compositions.

For the foregoing reasons, the rejection of claims 1, 2, 4-8, 10-13, 16-17, 22-23, 28-29, and 35-44 over *Cretois* in view of *Dubois* should be reversed.

C. Claim 14 Is Patentable over *Cretois* and *Dubois* in Further View of *Lai.*

Claim 14 remains rejected under 35 U.S.C. § 103 as allegedly being obvious over *Cretois* in view of *Dubois* in further view of *Lai*. Final Office Action at page 4 (*citing* the January Office Action).

Claim 14 stands alone from the other claims since it requires at least one angiotensin converting enzyme inhibitor chosen from a group of such inhibitors listed in the claim. Acknowledging its separate status, the Examiner has rejected this claim by itself. Final Office Action at 4.

Appellants incorporate herein their arguments that no motivation has been shown to combine *Cretois* and *Dubois*. Since that combination is necessary to support the *prima facie* case of obviousness against claim 14, Appellants respectfully contend that this rejection should be reversed.

This rejection also should be reversed because the combination proposed by the Examiner lacks motivation. *Lai* teaches "conjugates of physiologically compatible nitric oxide scavengers (e.g., dithiocarbamates (DC)) and pharmacologically active agents (e.g., NSAIDs)." *Lai* at col. 2, ll. 62-65. *Lai* describes captopril as an "angiotensin

converting enzyme inhibitor" (*id.* at col. 8, ll. 50-51) and minoxidil as a "vasodilator" (*id.* at col. 8, ll. 56 & 59). Accordingly, *Lai* does not teach combining captopril and minoxidil, since *Lai* requires a nitric oxide scavenger. This fact contrasts with the Examiner's proffer of motivation that "Lai teaches captopril and minoxidil are combinable." January Office Action at 5.

Moreover, *Lai* does not teach treating alopecia, so much as reducing alopecia as an unwanted side effect. At page 5 of the January Office Action, the Examiner cites *Lai* at column 3, which states: "There are a number of advantages of DC-adriamycin over adriamycin alone, including: (i) reducing cutaneous irritation and alopecia and vascular damage (because the conjugates are inactive until they have reached the intracellular site of action)[.]" Thus, *Lai* seeks to reduce the alopecia that occurs as a side-effect of the treatment with adriamycin, not treat the alopecia *per se*. In addition, minoxidil is disclosed for its vasodilating properties in a paragraph offset with "antihypertensive drugs." *Lai* at col. 8, ll. 44 & 59. Thus, minoxidil is not taught for its anti-alopecia properties either. Yet the Examiner alleges that the skilled artisan would be motivated to combine captopril and minoxidil according to appealed claim 14 "because of the expectation [of] treating alopecia and hypertension." January Office Action at 5. The disclosure of *Lai* does not provide the motivation alleged by the Examiner.

Because motivation has not been shown to make the combination set forth in Appellants' claim 14, this rejection should be reversed.

D. Claim 15 Is Patentable over *Cretois* and *Dubois* in Further View of *Ismail.*

Claim 15 remains rejected under 35 U.S.C. § 103 as allegedly being obvious over *Cretois* in view of *Dubois* in further view of *Ismail*. Final Office Action at page 4 (*citing* the January Office Action).

Claim 15 stands alone from the other claims since it requires at least one methylxanthine compound chosen from an enumerated group of such compounds. Acknowledging its separate status, the Examiner has rejected this claim by itself. Final Office Action at 4.

Appellants incorporate herein their arguments that no motivation has been shown to combine *Cretois* and *Dubois*. Since that combination is necessary to support the *prima facie* case of obviousness against claim 15, Appellants respectfully contend that this rejection also should be reversed.

This combination lacks the motivation alleged by the Examiner. Stating that *Ismail* teaches agents for the treatment and protection of skin, the Examiner alleges that "Exemplified is a capsule that can treat alopecia comprising pentoxifyllin, Vitamin E, and other ingredients. See [Ismail] Col. 8, example 24." January Office Action at 6. However, the connection between *Ismail's* example 24 and alopecia is tenuous at best. *Ismail* reveals "[t]he present invention relates to an agent containing vitamin E for treating and protecting the skin." *Ismail,* col. 1, ll. 18-19. Combinations of vitamin E with other active ingredients "are suitable as agents for the treatment of eczema, skin tetter, skin inflammations, itch, allergies, wrinkles, pigmentations in the skin and alopecia as well as wounds." *Id.* at col. 2, ll. 10-15. Pentoxifyllin is disclosed as an agent that can "promot[e] the blood circulation." *Id.* at col. 3, ll. 14 & 23. *Ismail* makes no connection between promoting blood circulation and treating alopecia. Nor is any connection made

between pentoxifyllin and alopecia. Thus, the Examiner's allegation that *Ismail's* example 24 can treat alopecia rests on mere conjecture. Accordingly, so does the requisite motivation to make the proposed combination. Mere conjecture does not replace the substantial evidence needed to support the *prima facie* case. *See* M.P.E.P. § 2144.03 (*discussing In re Zurko*, 258 F.3d 1379, 1385, 59 U.S.P.Q.2d (BNA) 1693, 1697 (Fed. Cir. 2001); *and In re Lee,* 277 F.3d 1338, 1344-45, 61 U.S.P.Q.2d (BNA) 1430, 1434-35 (Fed. Cir. 2002)).

Moreover, any reasonable expectation of success in this combination is destroyed by *Dubois.* The liposomes or vesicles of *Dubois* "minimize passage into the circulatory system." *Dubois* at col. 6, ll. 45-48. The Examiner has not shown how pentoxifyllin will promote blood circulation while it is inhibited from passing into the circulatory system.

Because this combination lacks motivation and reasonable expectation of success, the *prima facie* case has not been made. This rejection accordingly should be reversed.

E. Claim 19 Is Patentable over *Cretois* and *Dubois* in Further View of the '317 PCT Application.

Claim 19 remains rejected under 35 U.S.C. § 103 as being obvious over *Cretois* in view of *Dubois* in further view of the '317 PCT application. Final Office Action at page 5 (*citing* the January Office Action).

Claim 19 stands alone from the other claims since it requires at least one hair growth-promoting compound chosen from an enumerated group of such compounds.

Acknowledging its separate status, the Examiner has rejected this claim by itself. Final Office Action at 5.

Appellants incorporate herein their arguments that no motivation has been shown to combine *Cretois* and *Dubois*. Since that combination is necessary to support the *prima facie* case of obviousness against claim 19, Appellants respectfully contend that this rejection also should be reversed.

Moreover, the *prima facie* case fails for want of a teaching of all elements of the claimed invention. Claim 19 recites "an inner salt of 2,4-diamino-6-butoxy-3-sulfoxypyrimidine hydroxide." The '317 PCT application does not teach or suggest this compound, at least because pyrimidine contains two nitrogens in its ring, while the compounds disclosed by the '317 PCT application contain only one ring nitrogen. The Examiner's allegation that "[s]pecifically disclosed is 2,4-diamino-6-butoxy-3-sulfoxypyrimidien [sic] hydroxide" (January Office Action at 6) is incorrect. Therefore, the rejection should be reversed for that additional reason.

F. Claims 20-21 Are Patentable over *Cretois* and *Dubois* in Further View of the '701 PCT Application.

Claims 20 and 21 remain rejected under 35 U.S.C. § 103 as allegedly being obvious over *Cretois* in view of *Dubois* in further view of the '701 PCT application. Final Office Action at page 5 (*citing* the January Office Action).

Claims 20 and 21 stand separately from each other and from the other claims since they require at least one particular compound. Acknowledging their separate status, the Examiner has rejected these claims separately. Final Office Action at 5.

Appellants incorporate herein their arguments that no motivation has been shown to combine *Cretois* and *Dubois*. Since that combination is necessary to support the *prima facie* case of obviousness against claims 20 and 21, Appellants respectfully contend that this rejection should be reversed.

The limitations of claim 20 are not taught or suggested by the documents relied upon by the Examiner. Claim 20 recites "2,6-diamino-4-piperidinopyridine." The '701 PCT application teaches only 1,3,5-triazine compounds. *See* the '701 PCT application at Abstract. Accordingly, the *prima facie* case fails because all of the limitations of the rejected claim are not taught or suggested in the cited documents. *See* M.P.E.P. § 2143. For this additional reason, the rejection should be reversed as to claim 20.

The rejection as to claim 21 should be reversed for the additional reason that the alleged motivation lacks the "clear and particular" evidence required by the Federal Circuit in *In re Dembiczak*, 175 F.3d 994, 999, 50 U.S.P.Q.2d (BNA) 1614, 1617 (Fed Cir. 1999). The Examiner asserts that the three combined documents all relate to methods for treating alopecia. January Office Action at 5. However, it is not enough merely to find all of the limitations of a claimed invention in art purportedly directed to the same purpose. *See e.g., In re Geiger,* 815 F.2d at 688, 2 U.S.P.Q.2d at 1278. Instead, the Examiner must be able to point to "clear and particular" evidence that the skilled artisan would be motivated to make the claimed combination. *In re Dembiczak*, 175 F.3d at 999, 50 U.S.P.Q.2d at 1617. At most, the reason tendered by the Examiner make it obvious to try new combinations in general, but would not direct the skilled artisan to consider Appellants' claimed compositions.

CONCLUSION

A Petition for Extension of Time (One Month) accompanies this brief. If any extension of time under 37 C.F.R. § 1.136 is required to obtain entry of this appeal brief, such extension is hereby respectfully requested. If there are any fees due under 37 C.F.R. §§ 1.16 or 1.17 that are not enclosed herewith, including any fees required for an extension of time under 37 C.F.R. § 1.136, please charge such fees to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: December 15, 2003

By: _____
Jeremy M. Stipkala
Reg. No. 44,359

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Enclosures:

Appendix A (claims after June 2, 2003 Amendment).
Appendix B (claims after Amendment after Appeal filed herewith).
Exhibit 1 ("Vitamin E," THE MERCK INDEX, 12TH EDITION, *Merck Research Laboratories*, 10159, p. 1712 (Susan Budavari ed., 1996)).
Exhibit 2 (CHRISTOPHER K. MATHEWS & K.E. VAN HOLDE, BIOCHEMISTRY 674-78 (2d ed. 1996)).

Appendix A

The following represents the claims on appeal if Appellants' Amendment After Appeal is not entered.

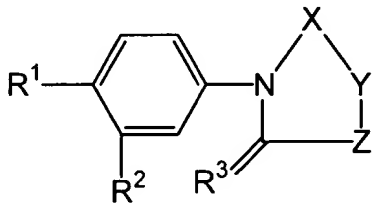
1. (Previously Presented) A composition comprising:

a) at least one physiologically tolerated film-forming agent;

b) at least one physiologically tolerated solvent;

c) at least one plasticizer; and

d) a compound of the formula I



(I)

or a stereoisomeric form or a physiologically tolerated salt of any of the foregoing, in which:

R^1 is
1) -CN,
2) $-NO_2$,
3) a halogen, or
4) $(C_1\text{-}C_4)$-alkyl-C(O)-OH;

R^2 is
1) $-CF_3$,
2) a halogen, or

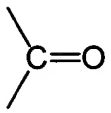
3) -CN;

R^3 is 1) =O,

2) =S, or

3) =NH;

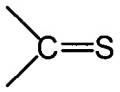
X is 1) a radical of formula II



(II)

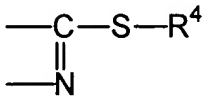
or

2) a radical of formula III



(III)

or X and Y together form a group of formula IV



(IV)

in which R^4 is 1) hydrogen atom,

2) (C_1-C_6)-alkyl-,

3) (C_2-C_6)-alkenyl-, or

4) $(C_1\text{-}C_6)$-alkyl-,

wherein the alkyl is mono- to trisubstituted by

4.1 -OH,

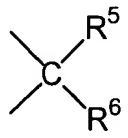
4.2 halogens,

4.3 -O-$(C_1\text{-}C_4)$-alkyl,

4.4 -CN, or

4.5 -SH;

Y is 1) a radical of formula V



(V)

in which:

R^5 is, independently of R^6, a hydrogen atom or $(C_1\text{-}C_4)$-alkyl, wherein the alkyl is unsubstituted or mono- to tetrasubstituted by halogens, and R^6 is, independently of R^5, $(C_1\text{-}C_4)$-alkyl, wherein the alkyl is unsubstituted or mono- to trisubstituted, by

a) halogens,

b) phenyl-$(CH_2)_m$-, wherein the phenyl is unsubstituted or mono- to trisubstituted, independently of one another, by

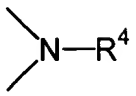
-COOH, -CN, or -CF_3, and m is the integer zero, 1, 2, 3, 4, 5, or 6,

c) -COOH,

d) -CN, or

e) -CF_3, or

2) radical of formula VI,

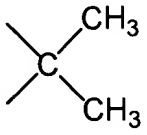


(VI)

in which R^4 is as defined above; and

Z is 1) -O- or

2) a radical of formula VII



(VII)

wherein said compound of formula I is released from the film formed by application of said composition to a skin surface.

2. (Original) A composition as claimed in claim 1, wherein the compound of formula I is a compound in which:

R^1 is 1) -CN,

2) $-NO_2$, or

3) a halogen;

R^2 is 1) $-CF_3$ or

2) a halogen;

R^3 is 1) =O or

2) =S;

X is the radical of formula II or III, or

X and Y together form the group of formula IV,

in which R^4 is as defined in claim 1;

Y is the radical of formula VI,

in which R^4 is as defined in claim 1; and

Z is the radical of formula VII.

3. (Withdrawn) A composition as claimed in claim 1, wherein the compound of formula I is a compound in which:

R^1 is -CN;

R^2 is $-CF_3$;

R^3 is =0;

X is the radical of formula II;

Y is the radical of formula VI, in which R^4 is hydrogen; and

Z is -O- or the radical of formula VII.

4. (Original) A composition as claimed in claim 1, wherein the compound of formula I is chosen from 4-[3-(4-hydroxybutyl)-4,4-dimethyl-2,5-dioxo-1-imidazolidinyl]-2-(trifluoromethyl)benzonitrile and 4-(5-methyl-2,4-dioxo-5-trifluoromethyl)-oxazolidin-3-yl)-2-(trifluoromethyl)-benzonitrile.

5. (Original) A composition as claimed in claim 1, wherein the at least one plasticizer is chosen from ethoxylated compounds, panthenol, esters of adipic acid, and esters of sebacic acid.

6. (Original) A composition as claimed in claim 5, wherein the at least one plasticizer is chosen from polyoxyethylated castor oil, ethoxylated cholesterol, and panthenol.

7. (Original) A composition as claimed in claim 1, wherein the at least one physiologically tolerated solvent is chosen from water and (C_1-C_6)-alcohols.

8. (Original) A composition as claimed in claim 7, wherein the (C_1-C_6)-alcohols are chosen from methanol, ethanol, propanol, isopropanol, butanol, pentanol, and hexanol.

9. (Withdrawn) A composition as claimed in claim 1, wherein the at least one physiologically tolerated film-forming agent comprises at least one naturally occurring substance chosen from alginic acid, alginates, collagen, collagen derivatives, hydrolyzed wheat proteins, carrageenan, cellulose, cellulose derivatives, chitosan, chitosan derivatives, keratin hydrolysates, protein hydrolysates, gelatin, guar gum, guar gum derivatives, hydrolyzed elastin, hydrolyzed milk proteins, hydrolyzed silk proteins, hydrolyzed soya proteins, hydrolyzed oat proteins, copolymers of hydroxyethylcellulose, dimethyldiallylammonium chloride, hyaluronic acid, hyaluronates, tragacanth, and xanthan.

10. (Original) A composition as claimed in claim 1, wherein the at least one physiologically tolerated film-forming agent comprises at least one synthetic substance chosen from acrylate/acrylamide copolymers, acrylate copolymers, acrylate/octylacrylamide copolymers, acrylic acid ester copolymers, methacrylic acid copolymers, adipic acid/dimethyl-aminohydroxypropyldiethylenetriamine copolymers, methacrylic acid/methacrylic acid ester copolymers neutralized with 2-amino-2-methylpropanol, polyacrylic acid crosslinked with pentaerythritol ethers or sugar allyl ethers, polysiloxane/polyalkyl polyether copolymers, polysiloxanes, ethylene/acrylic acid ester copolymers, ethylene/vinyl acetate copolymers, methacryloylethylbetaine/methacrylic acid copolymers, octylacrylamide/acrylic acid

ester/butylaminoethylmethacrylic acid copolymers, quaternized polyvinylpyrrolidone-dimethylaminoethylmethacrylic acid esters, polyvinylpyrrolidone/imidazolinium methochloride copolymers, sodium acrylate/dimethyldiallylammonium chloride copolymers, dimethyldiallylammonium chloride/sodium acrylate/acrylamide terpolymers, poly(dimethylsiloxane-copolyol-phospho-panthenoate), poly(methyl vinyl ether-maleic anhydride), poly(methyl vinyl ether-maleic acid monoalkyl ester), poly(vinylpyrrolidone), terpolymers based on pyrrolidone and acrylic acid compounds, poly(vinylpyrrolidone-dimethylaminoethylmethacrylic acid), polyvinylpyrrolidone/eicosene copolymers, polyvinylpyrrolidone/methacrylic acid ester/methacrylic acid terpolymers, poly-vinylpyrrolidone/hexadecene copolymers, polyvinylpyrrolidone/polycarbamyl polyglycol ester, polyvinylpyrrolidone/vinyl acetate copolymers, vinylimidazolium methochloride/vinylpyrrolidone copolymers, acrylic acid/acrylic acid ester copolymers and terpolymers of vinyl pyrrolidone, vinyl acetate, and vinyl propionate.

11. (Original) A composition as claimed in claim 1, further comprising at least one additive chosen from circulation-promoting compounds, angiotensin converting enzyme inhibitors, methylxanthine compounds, sodium channel openers, and hair growth-promoting compounds.

12. (Original) A composition as claimed in claim 11, wherein at least one circulation-promoting compound is chosen from dihydralazine, diisopropylamine, diazoxide, and calcium antagonists.

13. (Original) A composition as claimed in claim 12, wherein at least one calcium antagonist is chosen from nifedipine, nicardipine, verapamil, diltiazem, nisoldipine, nitrendipine, nivaldipine, isradipine, felodipine, nimodipine, gallopamil, fendiline, flunarizine, amlodipine, diperdipine, fluspirilene, primozide, fantofarone, nicergoline, cyclandelate, and 6-amino-4-piperidino-1,2-dihydro-1-hydroxy-2-iminopyrimidine.

14. (Original) A composition as claimed in claim 11, wherein at least one angiotensin converting enzyme inhibitor is chosen from quinapril, lisinopril, benzazepril, captopril, ramipril, fosinopril, cifazapril, and tradolapril.

15. (Original) A composition as claimed in claim 11, wherein at least one methylxanthine compound is chosen from pentoxifyllin, propentofyllin, and torbafyllin.

16. (Original) A composition as claimed in claim 11, wherein at least one sodium channel opener is chosen from 1-cyano-2-(1,1-dimethyl-propyl)-3-(3-pyridyl)guanidine and 5-alpha-reductase inhibitors.

17. (Original) A composition as claimed in claim 16, wherein at least one 5-alpha-reductase inhibitor is N-tert-butyl-3-oxo-4aza-5α-androst-1-ene-17β-carboxamide.

18. (Original) A composition as claimed in claim 11, wherein at least one hair growth-promoting compound is chosen from inner salts of 2,4-diamino-6-alkoxy-3-

sulfoxypyrimidine hydroxide having from 1 to 6 carbon atoms in the alkoxy radical, pyridine 1-oxide compounds, and 2,6-diamino-1,3,5-triazine compounds.

19. (Original) A composition as claimed in claim 18, wherein at least one hair growth-promoting compound is an inner salt of 2,4-diamino-6-butoxy-3-sulfoxypyrimidine hydroxide.

20. (Original) A composition as claimed in claim 18, wherein at least one pyridine 1-oxide compound is 2,6-diamino-4-piperidinopyridine.

21. (Original) A composition as claimed in claim 18, wherein at least one 2,6-diamino-1,3,5-triazine compound is 2,6-diamino-4-butoxy-1,3,5-triazine 1-oxide.

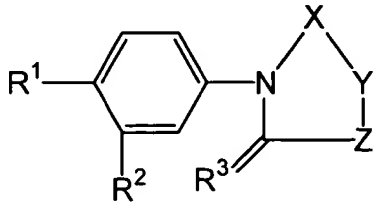
22. (Previously Presented) A process for making a product for treatment of androgenic alopecia, comprising the step of forming said product by bringing together:

a) at least one physiologically tolerated film-forming agent;

b) at least one physiologically tolerated solvent;

c) at least one plasticizer; and

d) a compound of the formula I



(I)

or a stereoisomeric form or a physiologically tolerated salt of any of the foregoing, in which:

R^1 is 1) -CN,

2) $-NO_2$,

3) a halogen, or

4) $(C_1\text{-}C_4)$-alkyl-C(O)-OH;

R^2 is 1) $-CF_3$,

2) a halogen, or

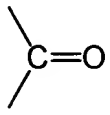
3) -CN;

R^3 is 1) =O,

2) =S, or

3) =NH;

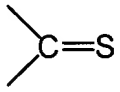
X is 1) a radical of formula II



(II)

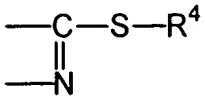
or

2) a radical of formula III



(III)

or X and Y together form a group of formula IV



(IV)

in which R^4 is 1) hydrogen atom,

2) $(C_1\text{-}C_6)$-alkyl-,

3) $(C_2\text{-}C_6)$-alkenyl-, or

4) $(C_1\text{-}C_6)$-alkyl-,

wherein the alkyl is mono- to trisubstituted by

4.1 -OH,

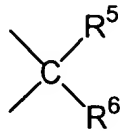
4.2 halogens,

4.3 -O-$(C_1\text{-}C_4)$-alkyl,

4.4 -CN, or

4.5 -SH;

Y is 1) a radical of formula V



(V)

in which:

R^5 is, independently of R^6, a hydrogen atom or $(C_1\text{-}C_4)$-alkyl, wherein the alkyl is unsubstituted or mono- to tetrasubstituted by halogens, and

R^6 is, independently of R^5, $(C_1$-$C_4)$-alkyl, wherein the alkyl is unsubstituted or mono- to trisubstituted, by

a) halogens,

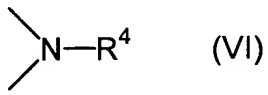
b) phenyl-$(CH_2)_m$-, wherein the phenyl is unsubstituted or mono- to trisubstituted, independently of one another, by -COOH, -CN, or $-CF_3$, and m is the integer zero, 1, 2, 3, 4, 5, or 6,

c) -COOH,

d) -CN, or

e) $-CF_3$, or

2) a radical of formula VI,

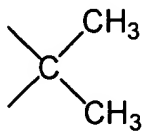


(VI)

in which R^4 is as defined above; and

Z is 1) -O- or

2) a radical of formula VII



(VII)

wherein said compound of formula I is released from the film formed by application of said composition to a skin surface.

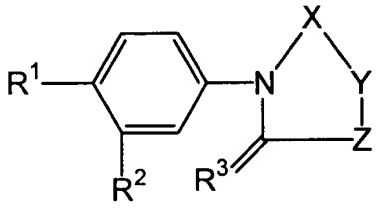
23. (Previously Presented) A process for making a product intended for treatment of seborrhea or acne, comprising the step of forming said product by bringing together:

a) at least one physiologically tolerated film-forming agent;

b) at least one physiologically tolerated solvent;

c) at least one plasticizer; and

d) a compound of the formula I



(I)

or a stereoisomeric form or a physiologically tolerated salt of any of the foregoing, in which:

R^1 is 1) -CN,

2) $-NO_2$,

3) a halogen, or

4) $(C_1\text{-}C_4)$-alkyl-C(O)-OH;

R^2 is 1) $-CF_3$,

2) a halogen, or

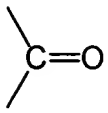
3) -CN;

R^3 is 1) =O,

2) =S, or

3) =NH;

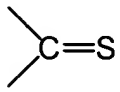
X is 1) a radical of formula II



(II)

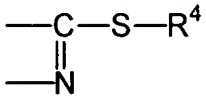
or

2) a radical of formula III



(III)

or X and Y together form a group of formula IV



(IV)

in which R^4 is 1) hydrogen atom,

2) $(C_1\text{-}C_6)$-alkyl-,

3) $(C_2\text{-}C_6)$-alkenyl-, or

4) $(C_1\text{-}C_6)$-alkyl-,

wherein the alkyl is mono- to trisubstituted by

4.1 -OH,

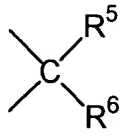
4.2 halogens,

4.3 -O-$(C_1\text{-}C_4)$-alkyl,

4.4 -CN, or

4.5 -SH;

Y is 1) a radical of formula V



(V)

in which:

R^5 is, independently of R^6, a hydrogen atom or $(C_1\text{-}C_4)$-alkyl, wherein the alkyl is unsubstituted or mono- to tetrasubstituted by halogens, and R^6 is, independently of R^5, $(C_1\text{-}C_4)$-alkyl, wherein the alkyl is unsubstituted or mono- to trisubstituted, by

a) halogens,

b) phenyl-$(CH_2)_m$-, wherein the phenyl is unsubstituted or mono- to trisubstituted, independently of one another, by

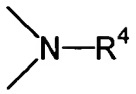
-COOH, -CN, or -CF_3, and m is the integer zero, 1, 2, 3, 4, 5, or 6,

c) -COOH,

d) -CN, or

e) -CF_3, or

2) radical of formula VI,

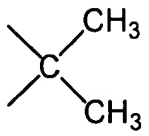


(VI)

in which R^4 is as defined above; and

Z is 1) -O- or

2) a radical of formula VII



(VII)

wherein said compound of formula I is released from the film formed by application of said composition to a skin surface.

24-27. (Cancelled)

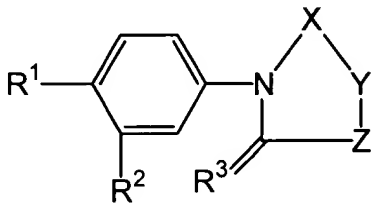
28. (Previously Presented) A process for treatment of seborrhea or acne, comprising the step of applying to a patient in need or desire thereof a composition comprising:

a) at least one physiologically tolerated film-forming agent;

b) at least one physiologically tolerated solvent;

c) at least one plasticizer; and

d) a compound of the formula I



(I)

or a stereoisomeric form or a physiologically tolerated salt of any of the foregoing, in which:

R^1 is 1) -CN,

2) $-NO_2$,

3) a halogen, or

4) $(C_1\text{-}C_4)$-alkyl-C(O)-OH;

R^2 is 1) $-CF_3$,

2) a halogen, or

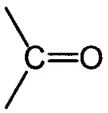
3) -CN;

R^3 is 1) =O,

2) =S, or

3) =NH;

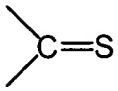
X is 1) a radical of formula II



(II)

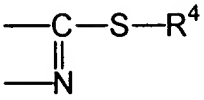
or

2) a radical of formula III



(III)

or X and Y together form a group of formula IV



(IV)

in which R^4 is 1) hydrogen atom,

2) $(C_1\text{-}C_6)$-alkyl-,

3) $(C_2\text{-}C_6)$-alkenyl-, or

4) $(C_1\text{-}C_6)$-alkyl-,

wherein the alkyl is mono- to trisubstituted by

4.1 -OH,

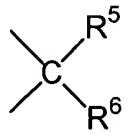
4.2 halogens,

4.3 -O-$(C_1\text{-}C_4)$-alkyl,

4.4 -CN, or

4.5 -SH;

Y is 1) a radical of formula V



(V)

in which:

R^5 is, independently of R^6, a hydrogen atom or $(C_1\text{-}C_4)$-alkyl, wherein the alkyl is unsubstituted or mono- to tetrasubstituted by halogens, and R^6 is, independently of R^5, $(C_1\text{-}C_4)$-alkyl, wherein the alkyl is unsubstituted or mono- to trisubstituted, by

a) halogens,

b) phenyl-$(CH_2)_m$-, wherein the phenyl is unsubstituted or mono- to trisubstituted, independently of one another, by

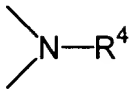
-COOH, -CN, or -CF_3, and m is the integer zero, 1, 2, 3, 4, 5, or 6,

c) -COOH,

d) -CN, or

e) -CF_3, or

2) radical of formula VI,

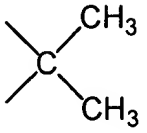


(VI)

in which R^4 is as defined above; and

Z is 1) -O- or

2) a radical of formula VII



(VII)

wherein said compound of formula I is released from the film formed by application of said composition to a skin surface.

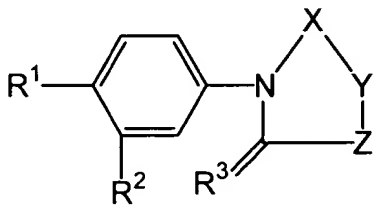
29. (Previously Presented) A cosmetic composition comprising:

a) at least one physiologically tolerated film-forming agent;

b) at least one physiologically tolerated solvent;

c) at least one plasticizer; and

d) a compound of the formula I



(I)

or a stereoisomeric form or a physiologically tolerated salt of any of the foregoing, in which:

R^1 is 1) -CN,

2) $-NO_2$,

3) a halogen, or

4) $(C_1\text{-}C_4)$-alkyl-C(O)-OH;

R^2 is 1) $-CF_3$,

2) a halogen, or

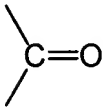
3) -CN;

R^3 is 1) =O,

2) =S, or

3) =NH;

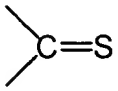
X is 1) a radical of formula II



(II)

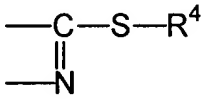
or

2) a radical of formula III



(III)

or X and Y together form a group of formula IV



(IV)

in which R^4 is 1) hydrogen atom,

2) (C_1-C_6)-alkyl-,

3) (C_2-C_6)-alkenyl-, or

4) (C_1-C_6)-alkyl-,

wherein the alkyl is mono- to trisubstituted by

4.1 -OH,

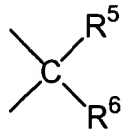
4.2 halogens,

4.3 -O-(C_1-C_4)-alkyl,

4.4 -CN, or

4.5 -SH;

Y is 1) a radical of formula V



(V)

in which:

R^5 is, independently of R^6, a hydrogen atom or (C_1-C_4)-alkyl, wherein the alkyl is unsubstituted or mono- to tetrasubstituted by halogens, and R^6 is, independently of R^5, (C_1-C_4)-alkyl, wherein the alkyl is unsubstituted or mono- to trisubstituted, by

a) halogens,

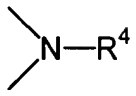
b) phenyl-$(CH_2)_m$-, wherein the phenyl is unsubstituted or mono- to trisubstituted, independently of one another, by -COOH, -CN, or -CF_3, and m is the integer zero, 1, 2, 3, 4, 5, or 6,

c) -COOH,

d) -CN, or

e) $-CF_3$, or

2) a radical of formula VI,

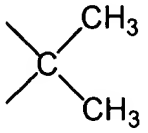


(VI)

in which R^4 is as defined above; and

Z is 1) -O- or

2) a radical of formula VII



(VII)

wherein said compound of formula I is released from the film formed by application of said composition to a skin surface.

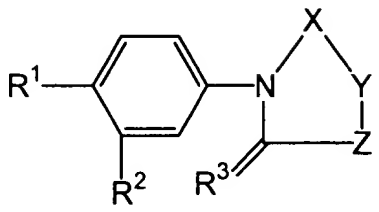
30. (Previously Presented) A method of treating skin substantially without hair cover comprising the step of applying to said skin of a patient in need or desire thereof a composition comprising:

a) at least one physiologically tolerated film-forming agent;

b) at least one physiologically tolerated solvent;

c) at least one plasticizer; and

d) a compound of the formula I



(I)

or a stereoisomeric form or a physiologically tolerated salt of any of the foregoing, in which:

R^1 is 1) -CN,

2) $-NO_2$,

3) a halogen, or

4) $(C_1\text{-}C_4)$-alkyl-C(O)-OH;

R^2 is 1) $-CF_3$,

2) a halogen, or

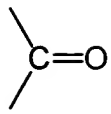
3) -CN;

R^3 is 1) =O,

2) =S, or

3) =NH;

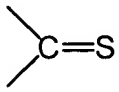
X is 1) a radical of formula II



(II)

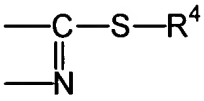
or

2) a radical of formula III



(III)

or X and Y together form a group of formula IV



(IV)

in which R^4 is

1) hydrogen atom,

2) $(C_1\text{-}C_6)$-alkyl-,

3) $(C_2\text{-}C_6)$-alkenyl-, or

4) $(C_1\text{-}C_6)$-alkyl-,

wherein the alkyl is mono- to trisubstituted by

4.1 -OH,

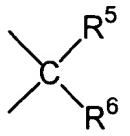
4.2 halogens,

4.3 -O-$(C_1\text{-}C_4)$-alkyl,

4.4 -CN, or

4.5 -SH;

Y is 1) a radical of formula V



(V)

in which:

R^5 is, independently of R^6, a hydrogen atom or $(C_1$-$C_4)$-alkyl, wherein the alkyl is unsubstituted or mono- to tetrasubstituted by halogens, and R^6 is, independently of R^5, $(C_1$-$C_4)$-alkyl, wherein the alkyl is unsubstituted or mono- to trisubstituted, by

a) halogens,

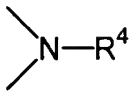
b) phenyl-$(CH_2)_m$-, wherein the phenyl is unsubstituted or mono- to trisubstituted, independently of one another, by -COOH, -CN, or $-CF_3$, and m is the integer zero, 1, 2, 3, 4, 5, or 6,

c) -COOH,

d) -CN, or

e) $-CF_3$, or

2) radical of formula VI,

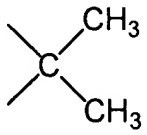


(VI)

in which R^4 is as defined above; and

Z is 1) -O- or

2) a radical of formula VII



(VII)

wherein said compound of formula I is released from the film formed by application of said composition to a skin surface.

31. (Previously Presented) A method of treating skin substantially without hair cover as claimed in claim 30, wherein the compound of formula I is a compound in which:

R^1 is 1) -CN,

2) $-NO_2$, or

3) a halogen;

R^2 is 1) $-CF_3$ or

2) a halogen;

R^3 is 1) =O or

2) =S;

X is the radical of formula II or III, or

X and Y together form the group of formula IV,

in which R^4 is as defined in claim 1;

Y is the radical of formula VI,

in which R^4 is as defined in claim 1; and

Z is the radical of formula VII.

32. (Previously Presented) A method of treating skin substantially without hair cover as claimed in claim 30, wherein the compound of formula I is a compound in which:

R^1 is -CN;

R^2 is $-CF_3$;

R^3 is =0;

X is the radical of formula II;

Y is the radical of formula VI, in which R^4 is hydrogen; and

Z is -O- or the radical of formula VII.

33. (Previously Presented) A method of treating skin substantially without hair cover as claimed in claim 30, wherein the compound of formula I is chosen from 4-[3-(4-hydroxybutyl)-4,4-dimethyl-2,5-dioxo-1-imidazolidinyl]-2-(trifluoromethyl)benzonitrile and 4-(5-methyl-2,4-dioxo-5-trifluoromethyl)-oxazolidin-3-yl)-2-(trifluoromethyl)-benzonitrile.

34. (Previously Presented) The method of treating skin substantially without hair cover as claimed in claim 30, wherein the composition further comprises at least one additive chosen from circulation-promoting compounds, angiotensin converting enzyme inhibitors, methylxanthine compounds, sodium channel openers, and hair growth-promoting compounds.

35. (Previously Presented) The method of treating skin substantially without hair cover as claimed in claim 34, wherein at least one hair growth-promoting compound is chosen from inner salts of 2,4-diamino-6-alkoxy-3-sulfoxypyrimidine hydroxide having from 1 to 6 carbon atoms in the alkoxy radical, pyridine 1-oxide compounds, and 2,6-diamino-1,3,5-triazine compounds.

36. (Previously Presented) The method of treating skin substantially without hair cover as claimed in claim 35, wherein at least one hair growth-promoting compound is an inner salt of 2,4-diamino-6-butoxy-3-sulfoxypyrimidine hydroxide.

37. (Previously Presented) The method of treating skin substantially without hair cover as claimed in claim 35, wherein at least one pyridine 1-oxide compound is 2,6-diamino-4-piperidinopyridine.

38. (Previously Presented) The method of treating skin substantially without hair cover as claimed in claim 35, wherein at least one 2,6-diamino-1,3,5-triazine compound is 2,6-diamino-4-butoxy-1,3,5-triazine 1-oxide.

Appendix B

The following represents the claims on appeal if Appellants' Amendment After Appeal is entered.

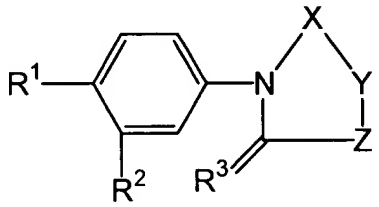
1. (Previously Presented) A composition comprising:

a) at least one physiologically tolerated film-forming agent;

b) at least one physiologically tolerated solvent;

c) at least one plasticizer; and

d) a compound of the formula I



(I)

or a stereoisomeric form or a physiologically tolerated salt of any of the foregoing, in which:

R^1 is
1) -CN,
2) $-NO_2$,
3) a halogen, or
4) $(C_1\text{-}C_4)$-alkyl-C(O)-OH;

R^2 is
1) $-CF_3$,
2) a halogen, or

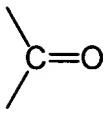
3) -CN;

R^3 is 1) =O,

2) =S, or

3) =NH;

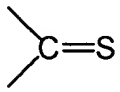
X is 1) a radical of formula II



(II)

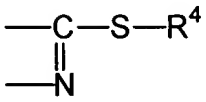
or

2) a radical of formula III



(III)

or X and Y together form a group of formula IV



(IV)

in which R^4 is 1) hydrogen atom,

2) (C_1-C_6)-alkyl-,

3) (C_2-C_6)-alkenyl-, or

4) $(C_1\text{-}C_6)$-alkyl-,

wherein the alkyl is mono- to trisubstituted by

4.1 -OH,

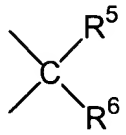
4.2 halogens,

4.3 -O-$(C_1\text{-}C_4)$-alkyl,

4.4 -CN, or

4.5 -SH;

Y is 1) a radical of formula V



(V)

in which:

R^5 is, independently of R^6, a hydrogen atom or $(C_1\text{-}C_4)$-alkyl, wherein the alkyl is unsubstituted or mono- to tetrasubstituted by halogens, and R^6 is, independently of R^5, $(C_1\text{-}C_4)$-alkyl, wherein the alkyl is unsubstituted or mono- to trisubstituted, by

a) halogens,

b) phenyl-$(CH_2)_m$-, wherein the phenyl is unsubstituted or mono- to trisubstituted, independently of one another, by

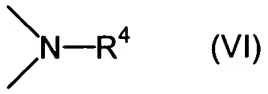
-COOH, -CN, or -CF_3, and m is the integer zero, 1, 2, 3, 4, 5, or 6,

c) -COOH,

d) -CN, or

e) -CF_3, or

2) radical of formula VI,

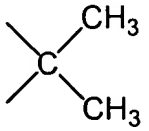


(VI)

in which R^4 is as defined above; and

Z is 1) -O- or

2) a radical of formula VII



(VII)

wherein said compound of formula I is released from the film formed by application of said composition to a skin surface.

2. (Original) A composition as claimed in claim 1, wherein the compound of formula I is a compound in which:

R^1 is 1) -CN,

2) $-NO_2$, or

3) a halogen;

R^2 is 1) $-CF_3$ or

2) a halogen;

R^3 is 1) =O or

2) =S;

X is the radical of formula II or III, or

X and Y together form the group of formula IV,

in which R^4 is as defined in claim 1;

Y is the radical of formula VI,

in which R^4 is as defined in claim 1; and

Z is the radical of formula VII.

3. (Withdrawn) A composition as claimed in claim 1, wherein the compound of formula I is a compound in which:

R^1 is -CN;

R^2 is $-CF_3$;

R^3 is =0;

X is the radical of formula II;

Y is the radical of formula VI, in which R^4 is hydrogen; and

Z is -O- or the radical of formula VII.

4. (Original) A composition as claimed in claim 1, wherein the compound of formula I is chosen from 4-[3-(4-hydroxybutyl)-4,4-dimethyl-2,5-dioxo-1-imidazolidinyl]-2-(trifluoromethyl)benzonitrile and 4-(5-methyl-2,4-dioxo-5-trifluoromethyl)-oxazolidin-3-yl)-2-(trifluoromethyl)-benzonitrile.

5. (Original) A composition as claimed in claim 1, wherein the at least one plasticizer is chosen from ethoxylated compounds, panthenol, esters of adipic acid, and esters of sebacic acid.

6. (Original) A composition as claimed in claim 5, wherein the at least one plasticizer is chosen from polyoxyethylated castor oil, ethoxylated cholesterol, and panthenol.

7. (Original) A composition as claimed in claim 1, wherein the at least one physiologically tolerated solvent is chosen from water and (C_1-C_6)-alcohols.

8. (Original) A composition as claimed in claim 7, wherein the (C_1-C_6)-alcohols are chosen from methanol, ethanol, propanol, isopropanol, butanol, pentanol, and hexanol.

9. (Withdrawn) A composition as claimed in claim 1, wherein the at least one physiologically tolerated film-forming agent comprises at least one naturally occurring substance chosen from alginic acid, alginates, collagen, collagen derivatives, hydrolyzed wheat proteins, carrageenan, cellulose, cellulose derivatives, chitosan, chitosan derivatives, keratin hydrolysates, protein hydrolysates, gelatin, guar gum, guar gum derivatives, hydrolyzed elastin, hydrolyzed milk proteins, hydrolyzed silk proteins, hydrolyzed soya proteins, hydrolyzed oat proteins, copolymers of hydroxyethylcellulose, dimethyldiallylammonium chloride, hyaluronic acid, hyaluronates, tragacanth, and xanthan.

10. (Currently Amended) A composition as claimed in claim 1, wherein the at least one physiologically tolerated film-forming agent comprises at least one synthetic substance chosen from acrylate copolymers, methacrylic acid copolymers, adipic acid/dimethyl-aminohydroxypropyldiethylenetriamine copolymers, polysiloxanes, ethylene/vinyl acetate copolymers, poly(methyl vinyl ether-maleic anhydride), poly(vinylpyrrolidone), polyvinylpyrrolidone/eicosene copolymers, and poly-vinylpyrrolidone/hexadecene copolymers.

11. (Original) A composition as claimed in claim 1, further comprising at least one additive chosen from circulation-promoting compounds, angiotensin converting enzyme

inhibitors, methylxanthine compounds, sodium channel openers, and hair growth-promoting compounds.

12. (Original) A composition as claimed in claim 11, wherein at least one circulation-promoting compound is chosen from dihydralazine, diisopropylamine, diazoxide, and calcium antagonists.

13. (Original) A composition as claimed in claim 12, wherein at least one calcium antagonist is chosen from nifedipine, nicardipine, verapamil, diltiazem, nisoldipine, nitrendipine, nivaldipine, isradipine, felodipine, nimodipine, gallopamil, fendiline, flunarizine, amlodipine, diperdipine, fluspirilene, primozide, fantofarone, nicergoline, cyclandelate, and 6-amino-4-piperidino-1,2-dihydro-1-hydroxy-2-iminopyrimidine.

14. (Original) A composition as claimed in claim 11, wherein at least one angiotensin converting enzyme inhibitor is chosen from quinapril, lisinopril, benzazepril, captopril, ramipril, fosinopril, cifazapril, and tradolapril.

15. (Original) A composition as claimed in claim 11, wherein at least one methylxanthine compound is chosen from pentoxifyllin, propentofyllin, and torbafyllin.

16. (Original) A composition as claimed in claim 11, wherein at least one sodium channel opener is chosen from 1-cyano-2-(1,1-dimethyl-propyl)-3-(3-pyridyl)guanidine and 5-alpha-reductase inhibitors.

17. (Original) A composition as claimed in claim 16, wherein at least one 5-alpha-reductase inhibitor is N-tert-butyl-3-oxo-4aza-5α-androst-1-ene-17β-carboxamide.

18. (Original) A composition as claimed in claim 11, wherein at least one hair growth-promoting compound is chosen from inner salts of 2,4-diamino-6-alkoxy-3-sulfoxypyrimidine hydroxide having from 1 to 6 carbon atoms in the alkoxy radical, pyridine 1-oxide compounds, and 2,6-diamino-1,3,5-triazine compounds.

19. (Original) A composition as claimed in claim 18, wherein at least one hair growth-promoting compound is an inner salt of 2,4-diamino-6-butoxy-3-sulfoxypyrimidine hydroxide.

20. (Original) A composition as claimed in claim 18, wherein at least one pyridine 1-oxide compound is 2,6-diamino-4-piperidinopyridine.

21. (Original) A composition as claimed in claim 18, wherein at least one 2,6-diamino-1,3,5-triazine compound is 2,6-diamino-4-butoxy-1,3,5-triazine 1-oxide.

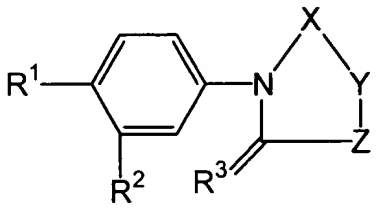
22. (Previously Presented) A process for making a product for treatment of androgenic alopecia, comprising the step of forming said product by bringing together:

a) at least one physiologically tolerated film-forming agent;

b) at least one physiologically tolerated solvent;

c) at least one plasticizer; and

d) a compound of the formula I



(I)

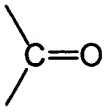
or a stereoisomeric form or a physiologically tolerated salt of any of the foregoing, in which:

R^1 is
1) -CN,
2) $-NO_2$,
3) a halogen, or
4) $(C_1\text{-}C_4)$-alkyl-C(O)-OH;

R^2 is
1) $-CF_3$,
2) a halogen, or
3) -CN;

R^3 is
1) =O,
2) =S, or
3) =NH;

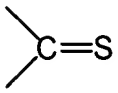
X is
1) a radical of formula II



(II)

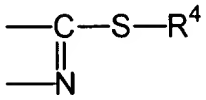
or

2) a radical of formula III



(III)

or X and Y together form a group of formula IV



(IV)

in which R^4 is 1) hydrogen atom,

2) $(C_1\text{-}C_6)$-alkyl-,

3) $(C_2\text{-}C_6)$-alkenyl-, or

4) $(C_1\text{-}C_6)$-alkyl-,

wherein the alkyl is mono- to trisubstituted by

4.1 -OH,

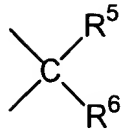
4.2 halogens,

4.3 -O-$(C_1\text{-}C_4)$-alkyl,

4.4 -CN, or

4.5 -SH;

Y is 1) a radical of formula V



(V)

in which:

R^5 is, independently of R^6, a hydrogen atom or $(C_1$-$C_4)$-alkyl, wherein the alkyl is unsubstituted or mono- to tetrasubstituted by halogens, and R^6 is, independently of R^5, $(C_1$-$C_4)$-alkyl, wherein the alkyl is unsubstituted or mono- to trisubstituted, by

a) halogens,

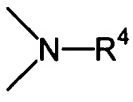
b) phenyl-$(CH_2)_m$-, wherein the phenyl is unsubstituted or mono- to trisubstituted, independently of one another, by -COOH, -CN, or $-CF_3$, and m is the integer zero, 1, 2, 3, 4, 5, or 6,

c) -COOH,

d) -CN, or

e) $-CF_3$, or

2) a radical of formula VI,

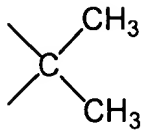


(VI)

in which R^4 is as defined above; and

Z is 1) -O- or

2) a radical of formula VII



(VII)

wherein said compound of formula I is released from the film formed by application of said composition to a skin surface.

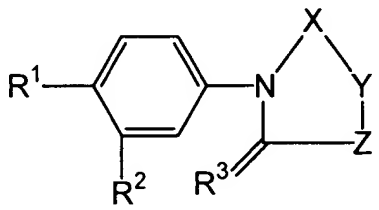
23. (Previously Presented) A process for making a product intended for treatment of seborrhea or acne, comprising the step of forming said product by bringing together:

a) at least one physiologically tolerated film-forming agent;

b) at least one physiologically tolerated solvent;

c) at least one plasticizer; and

d) a compound of the formula I



(I)

or a stereoisomeric form or a physiologically tolerated salt of any of the foregoing, in which:

R^1 is 1) -CN,

2) $-NO_2$,

3) a halogen, or

4) (C_1-C_4)-alkyl-C(O)-OH;

R^2 is 1) $-CF_3$,

2) a halogen, or

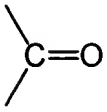
3) -CN;

R^3 is 1) =O,

2) =S, or

3) =NH;

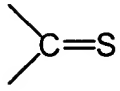
X is 1) a radical of formula II



(II)

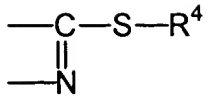
or

2) a radical of formula III



(III)

or X and Y together form a group of formula IV



(IV)

in which R^4 is 1) hydrogen atom,

2) $(C_1\text{-}C_6)$-alkyl-,

3) $(C_2\text{-}C_6)$-alkenyl-, or

4) $(C_1\text{-}C_6)$-alkyl-,

wherein the alkyl is mono- to trisubstituted by

4.1 -OH,

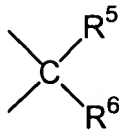
4.2 halogens,

4.3 -O-$(C_1\text{-}C_4)$-alkyl,

4.4 -CN, or

4.5 -SH;

Y is 1) a radical of formula V



(V)

in which:

R^5 is, independently of R^6, a hydrogen atom or $(C_1$-$C_4)$-alkyl, wherein the alkyl is unsubstituted or mono- to tetrasubstituted by halogens, and

R^6 is, independently of R^5, $(C_1$-$C_4)$-alkyl, wherein the alkyl is unsubstituted or mono- to trisubstituted, by

a) halogens,

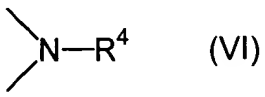
b) phenyl-$(CH_2)_m$-, wherein the phenyl is unsubstituted or mono- to trisubstituted, independently of one another, by -COOH, -CN, or $-CF_3$, and m is the integer zero, 1, 2, 3, 4, 5, or 6,

c) -COOH,

d) -CN, or

e) $-CF_3$, or

2) radical of formula VI,

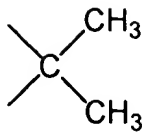


(VI)

in which R^4 is as defined above; and

Z is 1) -O- or

2) a radical of formula VII



(VII)

wherein said compound of formula I is released from the film formed by application of said composition to a skin surface.

24-27. (Cancelled)

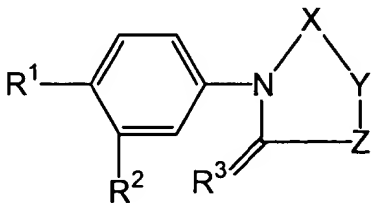
28. (Previously Presented) A process for treatment of seborrhea or acne, comprising the step of applying to a patient in need or desire thereof a composition comprising:

a) at least one physiologically tolerated film-forming agent;

b) at least one physiologically tolerated solvent;

c) at least one plasticizer; and

d) a compound of the formula I



(I)

or a stereoisomeric form or a physiologically tolerated salt of any of the foregoing, in which:

R^1 is 1) -CN,

2) $-NO_2$,

3) a halogen, or

4) $(C_1\text{-}C_4)$-alkyl-C(O)-OH;

R^2 is 1) $-CF_3$,

2) a halogen, or

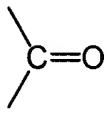
3) -CN;

R^3 is 1) =O,

2) =S, or

3) =NH;

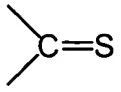
X is 1) a radical of formula II



(II)

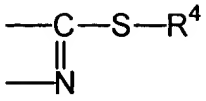
or

2) a radical of formula III



(III)

or X and Y together form a group of formula IV



(IV)

in which R^4 is 1) hydrogen atom,

2) $(C_1\text{-}C_6)$-alkyl-,

3) $(C_2\text{-}C_6)$-alkenyl-, or

4) $(C_1\text{-}C_6)$-alkyl-,

wherein the alkyl is mono- to trisubstituted by

4.1 -OH,

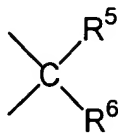
4.2 halogens,

4.3 -O-$(C_1\text{-}C_4)$-alkyl,

4.4 -CN, or

4.5 -SH;

Y is 1) a radical of formula V



(V)

in which:

R^5 is, independently of R^6, a hydrogen atom or $(C_1$-$C_4)$-alkyl, wherein the alkyl is unsubstituted or mono- to tetrasubstituted by halogens, and R^6 is, independently of R^5, $(C_1$-$C_4)$-alkyl, wherein the alkyl is unsubstituted or mono- to trisubstituted, by

a) halogens,

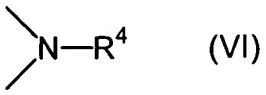
b) phenyl-$(CH_2)_m$-, wherein the phenyl is unsubstituted or mono- to trisubstituted, independently of one another, by -COOH, -CN, or $-CF_3$, and m is the integer zero, 1, 2, 3, 4, 5, or 6,

c) -COOH,

d) -CN, or

e) $-CF_3$, or

2) radical of formula VI,

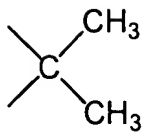


(VI)

in which R^4 is as defined above; and

Z is 1) -O- or

2) a radical of formula VII



(VII)

wherein said compound of formula I is released from the film formed by application of said composition to a skin surface.

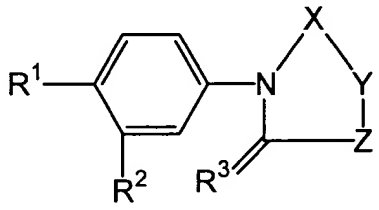
29. (Previously Presented) A cosmetic composition comprising:

a) at least one physiologically tolerated film-forming agent;

b) at least one physiologically tolerated solvent;

c) at least one plasticizer; and

d) a compound of the formula I



(I)

or a stereoisomeric form or a physiologically tolerated salt of any of the foregoing, in which:

R^1 is 1) -CN,

2) $-NO_2$,

3) a halogen, or

4) $(C_1\text{-}C_4)$-alkyl-C(O)-OH;

R^2 is 1) $-CF_3$,

2) a halogen, or

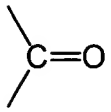
3) -CN;

R^3 is 1) =O,

2) =S, or

3) =NH;

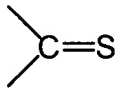
X is 1) a radical of formula II



(II)

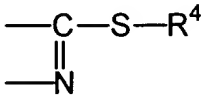
or

2) a radical of formula III



(III)

or X and Y together form a group of formula IV



(IV)

in which R^4 is 1) hydrogen atom,

2) $(C_1\text{-}C_6)$-alkyl-,

3) $(C_2\text{-}C_6)$-alkenyl-, or

4) $(C_1\text{-}C_6)$-alkyl-,

wherein the alkyl is mono- to trisubstituted by

4.1 -OH,

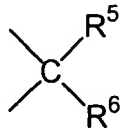
4.2 halogens,

4.3 -O-$(C_1\text{-}C_4)$-alkyl,

4.4 -CN, or

4.5 -SH;

Y is 1) a radical of formula V



(V)

in which:

R^5 is, independently of R^6, a hydrogen atom or $(C_1\text{-}C_4)$-alkyl, wherein the alkyl is unsubstituted or mono- to tetrasubstituted by halogens, and R^6 is, independently of R^5, $(C_1\text{-}C_4)$-alkyl, wherein the alkyl is unsubstituted or mono- to trisubstituted, by

a) halogens,

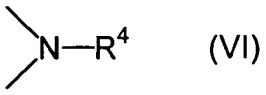
b) phenyl-$(CH_2)_m$-, wherein the phenyl is unsubstituted or mono- to trisubstituted, independently of one another, by -COOH, -CN, or $-CF_3$, and m is the integer zero, 1, 2, 3, 4, 5, or 6,

c) -COOH,

d) -CN, or

e) $-CF_3$, or

2) a radical of formula VI,

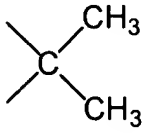


(VI)

in which R^4 is as defined above; and

Z is 1) -O- or

2) a radical of formula VII



(VII)

wherein said compound of formula I is released from the film formed by application of said composition to a skin surface.

30.-38. (Canceled)

39. (New) A composition as claimed in claim 1, wherein the at least one physiologically tolerated film-forming agent comprises at least one synthetic substance chosen from acrylate/acrylamide copolymers, methacrylic acid/methacrylic acid ester copolymers neutralized with 2-amino-2-methylpropanol, polysiloxane/polyalkyl polyether copolymers, ethylene/acrylic acid ester copolymers, polyvinylpyrrolidone/imidazolinium methochloride copolymers, sodium acrylate/dimethyldiallylammonium chloride copolymers, poly(methyl vinyl ether-maleic acid monoalkyl ester), and poly(vinylpyrrolidone-dimethylaminoethylmethacrylic acid).

40. (New) A composition as claimed in claim 1, wherein the at least one physiologically tolerated film-forming agent comprises at least one synthetic substance chosen from acrylate/octylacrylamide copolymers, quaternized polyvinylpyrrolidone-dimethylaminoethylmethacrylic acid esters, poly(dimethylsiloxane-copolyol-phospho-panthenoate), and vinylimidazolium methochloride/vinylpyrrolidone copolymers.

41. (New) A composition as claimed in claim 1, wherein the at least one physiologically tolerated film-forming agent comprises at least one synthetic substance chosen from acrylic acid ester copolymers, and polyvinylpyrrolidone/methacrylic acid ester/methacrylic acid terpolymers.

42. (New) A composition as claimed in claim 1, wherein the at least one physiologically tolerated film-forming agent comprises at least one synthetic substance chosen from polyacrylic acid crosslinked with pentaerythritol ethers or sugar allyl ethers, terpolymers based on pyrrolidone and acrylic acid compounds, and polyvinylpyrrolidone/vinyl acetate copolymers.

43. (New) A composition as claimed in claim 1, wherein the at least one physiologically tolerated film-forming agent comprises at least one synthetic substance chosen from polyvinylpyrrolidone/polycarbamyl polyglycol ester, and acrylic acid/acrylic acid ester copolymers.

44. (New) A composition as claimed in claim 1, wherein the at least one physiologically tolerated film-forming agent comprises at least one synthetic substance chosen from methacryloylethylbetaine/methacrylic acid copolymers, dimethyldiallylammonium chloride/sodium acrylate/acrylamide terpolymers, octylacrylamide/acrylic acid ester/butylaminoethylmethacrylic acid copolymers, and terpolymers of vinyl pyrrolidone, vinyl acetate, and vinyl propionate.